

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

**In re Application of:**

John Barthelow CLASSEN

**Application No.:** 10/081,705

Group Art Unit: 2161

**Filed:** 02/21/2002

Examiner: LEROUX, Etienne Pierre

**Title:** COMPUTER ALGORITHMS AND METHODS FOR PRODUCT SAFETY

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**SUPPLEMENTAL INFORMATION DISCLOSURE**

Sir:

Applicant previously filed Information Disclosure Statements on September 23, 2004; November 2, 2004 and July 28, 2005.

Applicant now attaches additional references for the Examiner's review. In addition, the reference identified as Reference Number 4, previously submitted by Applicant in the Supplemental Information Disclosure Statement dated September 23, 2004, is being resubmitted because it was not initialed by the Examiner as being reviewed. Accordingly, the reference is again included in this Supplemental Information Disclosure Statement to ensure the reference has been reviewed by the Examiner.

A check in the amount of \$180.00 is enclosed for payment of the necessary fee.

02/03/2006 SHASSEN1 00000070 10081705

01 FC:1806

180.00 0P

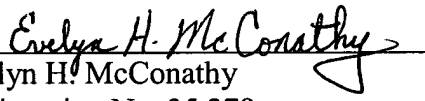
**CONCLUSION**

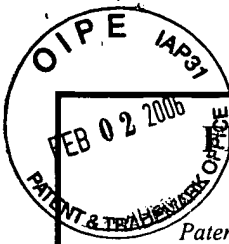
It is respectfully requested that the information be considered by the Examiner and that a copy of the attached Form PTO-1449 be returned indicating that said references have been considered.

Applicants' undersigned attorney may be reached by telephone at (215) 988-2700. All correspondence should be directed to the below-listed address.

Respectfully submitted,

Dated: January 30, 2006

  
Evelyn H. McConathy  
Registration No. 35,279  
DRINKER BIDDLE & REATH LLP  
One Logan Square  
18<sup>th</sup> and Cherry Streets  
Philadelphia, PA 19103-6996  
Tel: (215) 988-3361  
Fax: (215) 988-2757

**FEE TRANSMITTAL  
for FY 2005**

Patent fees are subject to annual revision.

☒ Applicant claims small entity status. See 37 CFR 1.27

Complete if known

Application Number	10/081,705
Filing Date	02/21/2002
First Named Inventor	CLASSEN
Examiner Name	LEROUX, ETIENNE PIERRE
Art Unit	2161

**TOTAL AMOUNT OF PAYMENT** (\$180.00)

Attorney Docket No. 204984[22499-68466]

**METHOD OF PAYMENT** (check all that apply)☒ Check ☐ Credit Card ☐ Money Order ☐ None ☐ Other (please identify): \_\_\_\_\_☐ Deposit Account:Deposit Account Number **50-0573**Deposit Account Name **Drinker Biddle & Reath LLP**

For the above-identified deposit account, the Director is hereby authorized to: (check all that apply)

<input checked="" type="checkbox"/> Charge fee(s) indicated below	<input type="checkbox"/> Charge fee(s) indicated below, except for the filing fee
<input checked="" type="checkbox"/> Charge any additional fee required under 37 CFR 1.16 and 1.17	<input checked="" type="checkbox"/> Credit any overpayments

**FEE CALCULATION****1. Basic Filing, Search and Examination Fees**

Application Type	Filing Fees		Search Fees		Examination Fees		Fees Paid
		Small Entity		Small Entity		Small Entity	
Utility	300	150	500	250	200	100	\$500.00
Design	200	100	100	50	130	65	
Plant	200	100	300	150	160	80	
Reissue	300	150	500	250	600	300	
Provisional	200	100	0	0	0	0	

**2. Excess Claim Fees**

Fee Description		Small Entity
Each claim over 20 or, for Reissues, each claim over 20 and more than in the original patent	50	25
Each independent claim over 3 or, for Reissues, each independent claim more than in the original patent	200	100
Multiple dependent claims	360	180

Total Claims	Extra Claims	Fee	Fee Paid	Multiple Dependent Claims	
* - 20 =	* x	* =	*	Fee	Fee Paid
					0

Indep. Claims	Extra Claims	Fee	Fee Paid
8 - 3 =	* x	*	*

**3. Application Size Fee**

If the specification and drawings exceed 100 sheets of paper, the application size fee due is \$250 (\$125 for small entity) for each additional 50 sheets or fraction thereof.

Total Sheets	Extra Sheets	Number of each additional 50 or fraction thereof	Fee	Fee Paid
* - 100 =	* / 50 =	* (round up to a whole number) x	125	0

**4. Other Fee(s)**

Non-English Specification, \$130 fee (no small entity discount)

Other: Information Disclosure StatementFees Paid180.00

SUBMITTED BY CUSTOMER NO. 23973

Complete (if applicable)

Name (Print/Type)	EVELYN H. MCCONATHY	Registration No. (Attorney/Agent)	35,279	Telephone	(215) 988.2700
Signature	<i>Evelyn H. McConathy</i>			Date	January 30, 2006

U.S. Department of Commerce

Date Filed: January 30, 2006DOCKET NO. 204984  
[formerly 22499-68466]

APPLN. NO. 10/081,705

APPLICANT: John Barthelow CLASSEN

FILING DATE: 02/21/2002

GROUP 2161

## U.S. PATENT DOCUMENTS

Examiner Initial		Document Number	Date	Name	Class	Subclass	Filing Date if appropriate
	A	5,723,283	03/03/1998	CLASSEN	435	4	
	B	5,728,385	03/17/1998	CLASSEN	424	201.1	
	C	6,219,674	04/17/2001	CLASSEN	707	104	
	D	6,584,472	04/24/2003	CLASSEN	707	104.1	
	E	90/007,638	07/22/2005	CLASSEN			
	F	90/007,639	07/22/2005	CLASSEN			
<b>OTHER DOCUMENT(S)</b> (Including Author, Title, Date, Pertinent Pages, etc.)							
	1	<i>Baker v. Secy of Dept. of Health and Human Servs.</i> , No. 99-653V, 2003 WL 22416622, (Ct. Fed. Cl. Sept. 26, 2003)					
	2	A. Bate, et al., "A Bayesian neural network method for adverse drug reaction signal generation," <i>Eur J Clin Pharmacol</i> 54(4) (June 1998) 315-321					
	3	C. Baum, et al., "The Spontaneous Reporting System in the United States," <i>Pharmacoepidemiology</i> , 2nd ed. New York: John Wiley & Sons, 1994, 125-137					
	4	D. Bradbury, "A Bitter Pill to Swallow," <i>Computing</i> , 34-35, February 9, 1995					
	5	D. Classen et al., "Adverse Drug Events in Hospitalized Patients," 277 <i>JAMA</i> , 301-306 (1997)					
	6	D. Classen et al., "Computerized Surveillance of Adverse Drug Events in Hospital Patients," 266 <i>JAMA</i> 2847-2851 (1991)					
	7	D. Classen et al., "Description of a Computerized Adverse Drug Event Monitor Using a Hospital Information System," 27 <i>Hosp. Pharm.</i> 774, 776-779, 783 (1992)					
	8	D. Classen & S. Pestotnik, "The Computer-Based Patient Record," <i>Hospital Epidemiology and Infection Control</i> , 141-154 (2nd Ed., New York: Lippincott Williams & Williams 1999)					
	9	R. Evans et al., "A Computer-Assisted Management Program for Antibiotics and Other Antiinfective Agents," 338 <i>The New England Journal of Medicine</i> , 232-238 (1998)					
	10	R. Evans et al., "Development of Computerized Adverse Drug Event Monitor," 15 <sup>th</sup> <i>Annual Symposium on Computer Applications in Medical Care</i> , 23-27 (1992)					
	11	R. Evans et al., "Evaluation of a Computer-Assisted Antibiotic-Dose Monitor," 33, <i>Annals. Pharm.</i> , 1026-1031 (1999)					
	12	R. Evans et al., "Preventing Adverse Drug Events in Hospitalized Patients," 28 <i>Ann. Pharm.</i> 523-527 (1994)					
	13	R. Evans et al., "Prevention of Adverse Drug Events through Computerized Surveillance," 16 <sup>th</sup> <i>Annual Symposium of Computer Applications in Medical Care</i> , 437-441 (1993)					
	14	R. Evans et al., "Using a Hospital Information System to Assess the Effects of Adverse Drug Events," <i>Seventeenth Annual Symposium on Computer Applications in Medical Care</i> , 161-165 (1994)					
	15	G. Faich, US Adverse Drug Reaction Surveillance 1989-1994, <i>Pharmacoepidemiology and Drug Safety</i> 5:393-398 (1996)					
	16	Federal Register, vol. 58, no. 105, docket no. 93N-0072 (June 3, 1993)					
	17	Finney, D. J. Systematic Signalling of Adverse Reactions to Drugs, <i>Methods of Information in Medicine</i> , 13 (1974) 1-10					
	18	International Reporting of Adverse Drug Reactions, Final Report of CIOMS Working Group, 1990					
	19	Jim Kling, "From hypertension to angina to Viagra," <i>Modern Drug Discovery</i> 1(2) (1998), available at <a href="http://pubs.acs.org/hotartcl/mdd/98/novdec/viagra.htm">http://pubs.acs.org/hotartcl/mdd/98/novdec/viagra.htm</a>					
	20	M. Lindquist et al., "From Association to Alert—A Revised Approach to International Signal Analysis," <i>Pharmacoepidemiology and Drug Safety</i> 8:S15-S25 (April 1999)					
	21	David J. Morrow, "New Profits in Old Bottles," <i>N.Y. Times</i> , March 19, 1999					
<b>Examiner Signature:</b>					<b>Date Considered:</b>		

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant(s).

PTO-1449.doc

Date Filed: January 30, 2006

APPLN. NO. 10/081,705

**APPLICANT: John Barthelow CLASSEN**

FILING DATE: 02/21/2002

**GROUP 2161**

**OTHER DOCUMENT(S)** *(Including Author, Title, Date, Pertinent Pages, etc.)*

- |    |   |
|----|---|
| 22 | C.A. Naranjo et al., "A method for estimating the probability of adverse drug reactions," 30 <i>Clin. Pharmacol. Ther.</i> (2):239-45 (1981)  |
| 23 | V. Pinkston & E. J. Swain, "Management of Adverse Drug Reaction and Adverse Event Data through Collection, Storage and Retrieval," <i>Detection of New Adverse Drug Reactions</i> , 281-296 (April 1998) (4th Ed., London: Macmillan Reference Ltd.)  |
| 24 | "Post-marketing surveillance for adverse events after vaccination: the national Vaccine Adverse Event Reporting System (VAERS)," MEDWATCH Continuing Education Article (1998)   |
| 25 | <i>Statement of Susan S. Ellenberg before the U.S. House of Representatives, available at <a href="http://www.fda.gov/ola/1999/anthrax.html">www.fda.gov/ola/1999/anthrax.html</a></i> (July 21, 1999)  |
| 26 | A. Szarfman, "Discussion: A Report on the Activities of the Adverse Events Working Groups: Focus on Improving the Detection of Rare but Serious Events," 1999 Proceedings of the Biopharmaceutical Section, American Statistical Association, Alexandria (VA), <i>American Statistical Association</i> , 12-13 (1999) (Szarfman/abstract) |
| 27 | A. Szarfman, "New Methods for Signal Detection," <i>15<sup>th</sup> International Conference on Pharmacoepidemiology</i> , Boston, Mass., August 28, 1999 (Szarfman/ppt)  |
| 28 | U.S. Food and Drug Administration, "What Is A Serious Adverse Event?," <a href="http://www.fda.gov/medwatch/report/DESK/advevnt.htm">http://www.fda.gov/medwatch/report/DESK/advevnt.htm</a>  |
| 29 | Vaccine Safety Forum, Summaries of Two Workshops, Washington, DC (National Academy Press 1997)  |

**Examiner Signature:**

**Date Considered:**

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant(s).